Revised June 2022

HUNTER COLLEGE
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE
PROTOCOL REVIEW FORM

Provide a response to every question, using NA (Not Applicable) where appropriate. Format your text so that the responses to each question are printed using a typeface (e.g., bold, italics) that produces good contrast between the questions and responses.

PART I: PROJECT IDENTIFICATION

1 Project Title (Do not exceed 56 spaces):

2 Faculty member responsible for project:

3 Department:

4 College telephone number:

5 Emergency telephone number:

6. Other individuals to be notified in emergencies:

7 For all personnel indicate the following:
A. Name:
B. Phone Number
C. E-mail address: _____
D. Status: (Faculty, technician, undergraduate, graduate student, postdoc, etc).
E. Animal care certified at Hunter? Yes ☐ No ☐
F. Qualifications/experience relevant to the procedures proposed in this protocol:
G. Specific role on protocol--procedures which he/she will carry out (e.g., which specific behavioral tests, surgeries):

H. If the individual has not carried out these procedures before, who is responsible for training him/her?

8 Cooperating Institution (Please attach a copy of its protocol form and the notification you received).

9. Proposed duration (maximum of 36 months):

10. This project is: __New; ___Renewal of Protocol #_____; Revision of Protocol # _____.
Note: If a revision, please highlight the revised information.
11. Purpose of application:
a. A grant from or application to (Please provide your grant # or the name of the funding agency to which you applied):

b. An undergraduate student project

c. A course activity (Provide course number). If you wish students to handle the animals at any time: 1) they must receive appropriate preparatory training and 2) this training and students' role in handling the animals must be described in your protocol).

d. A graduate student project

e. An approved Doctoral Dissertation project. Indicate Program, Supervisor's name and Department

f. Other

Part II: Project Justification
Questions 12-19 are designed to elicit an account of the project, written in terms understandable to a non-specialist colleague or lay member of IACUC. Define all scientific terms at first use. Please try to confine this section to no more than 2 single-spaced pages.

12. Introduction and rationale: In one or two brief paragraphs, provide background information describing the general nature and significance of the project.

13. Specific Aims: Describe, in a series of brief, numbered statements, the scientific goals of your project.

14. If this is a continuation of previous work in your lab, please provide a brief summary of the scientific progress you have made on this project. Please include a description of any unforeseen animal welfare issues which you encountered.

15. Justification of animal use. Explain why animals must be used for these studies, and why non-animal models cannot be used. Justify the choice of species.

16. Animal Use/Methodology: Provide a complete description of how the animals will be used at all stages of the project, including all experimental and surgical procedures. These should be specified in sufficient detail so that the committee can understand what the animals will experience. If these methods are stressful or painful, please respond fully to the questions in Part IV of the form.

17. Explain how these procedures will help provide answers to the questions raised by the Specific Aims of this project.

18 Experimental Design: **Summarize in tabular form** the Experimental Design of the project, indicating treatment groups and maximal numbers of animals per group. (Please do not include methodological detail here**; it should be provided in 16**.)

19.
a. Justify the number (and sex) of animals used in relation to the Specific Aims and Experimental Design. If you are using only males or only females as experimental subjects, please justify. Please list any measures you are using to reduce animal numbers. (This can include such things as reducing extraneous variables which would be expected to confound results, increase variability, and require greater animal numbers to demonstrate significant differences between groups, using inbred strains

when available, or using a within subjects design.)

(19.a.1)Provide total number and number per group **(include table)**

(19.a.2) Statistical Programs that will be used to analyze data from this study (e.g. Student t test, analysis of variance, regression, etc.):

(19.a.3) Provide the power analysis to indicate how the number of animals was determined:

Alpha level:

Beta or power level:

Primary outcome variable:

Effect size or change expected:

Resulting number per group:

Total number:

(19.a.4) If you will not use statistics or you did not perform a power analysis, please justify and describe how the number of animals was determined:

(19.a.5) If you consulted a statistician, please provide name:_____.

20. Scientific or Biomedical Contribution: Describe, in a brief paragraph, the contribution of the project to human or animal health, to the advancement of knowledge or the good of society.

21. Assurance of non-duplication of research (If you check c, d, or e, please also supply the requested information):

a. These experiments or observations have not been done previously in any species.

b. These experiments or observations have not been done previously in this species.

c. Previous experiments were inconclusive. (Explain why these experiments should provide conclusive results.)
d. Although similar to previous experiments, the present research is designed to provide additional data. (Describe new data)
e. The animals are being used for teaching/training purposes.
f. Other (Provide an explanation)

22. Please provide evidence of your familiarity with the current literature in this area by summarizing a recent literature search. Your description should include: 1) keywords used, 2) databases searched, 3) period of literature covered, 4) date of search and/or experts consulted, 5) number of "hits" or list of pertinent articles. **If proposed procedures will cause pain and/or distress, keywords should be skillfully selected to elicit potential procedural alternatives.**

The goal of the literature search is to provide evidence that your proposal does not unnecessarily duplicate previous work and document that you have considered alternatives to the use of animals. The theory of alternatives is based on the concept of the three R's first described by Russell and Burch in their 1959 book The Principles of Humane Experimental Technique. The three R's are Reduction in animal numbers; Refinement of methods to minimize pain and distress to the animals; and Replacement of the animal model with a non-animal model or a phylogenetically lower species. Your keywords should suggest the search for all three types of alternatives as well as the search for prior research. A good internet site for information on alternatives is the Alternatives to Animal Testing Web Site (https://caat.jhsph.edu/) which was created to serve as a gateway to alternatives news, information, and resources on the Internet and beyond. Another useful site is the Animal Welfare Information Center (AWIC) (https://www.nal.usda.gov/programs/awic). AWIC is mandated by the Animal Welfare Act (AWA) to provide information for improved animal care and use in research, testing, teaching, and exhibition. Databases vary widely in their coverage and complimentary sources should be sought. For additional assistance or advice on performing electronic database searches, you can contact the Science Reference Librarian.

Part III: ANIMAL TREATMENT INFORMATION

23 Species:
a. Strain:
b. Sex: Males ◯ Females ◯
c. Average weight:
d. Age/s:
e. Maximum number of animals to be housed at one time. Males (N=); Females (N=) Location: ____Central Facility; _____Satellite
f. If animals are to be taken from their animal room at any time for testing or other procedures, where will they be taken _____ and for how long _____?
g. Special housing required: Describe (discuss with the facility manager before submitting protocol).
h. Maximum number of research animals in protocol year:
i. Maximum number of associated animals: (e.g., unused littermates; breeding stock used to provide research animals).
j. Vendor or animal source (Any change in approved source must be approved by veterinarian and Facility Manager.):

24.
a. Drugs/Hormones/Medications to be used in the course of the research.
DRUGS/ MEDICATION
DOSAGE
ROUTE OF ADMINISTRATION
RESPONSIBLE INDIVIDUAL

1) Controlled Substances

a. Any DEA controlled substance needs approval from the Hunter College Environmental and Safety Officer, Room 1211A, 212 772-4462. A Standard Operating Procedure statement (SOP) is required. Please attach a copy of the approval letter.

b. Biological materials (For cell lines, please provide source species and strain, vendor, purity checks, potential hazards, etc.)

25. Euthanasia:
a. Even if animals are not normally euthanized in the course of the proposed work, all protocols must provide a method of euthanasia to be used in case animals become sick or injured during the course of the research.

1) List method(s) to be used and person(s) responsible. Public Health Service Policy requires that methods of euthanasia conform to the most recent A.V.M.A. recommendations (https://www.avma.org/sites/default/files/2020-02/Guidelines-on-Euthanasia-2020.pdf).

2) If drugs are used describe dosage and route of administration.

3) If animals are euthanized by cervical dislocation or decapitation without prior anesthetization, provide a scientific justification for withholding anesthesia.

4) If alternative methods (e.g., not listed are used, the method must be fully described, and its need justified. Please consult with the facilities manager or veterinarian if you have any questions.

b. What criteria will you use to determine that the animal is dead if decapitation or exsanguination is not used (e.g., cessation of heartbeat or respiration for a suitable period of time)?

26. Disposition other than euthanasia. Check as many as applicable and indicate species if this protocol involves more than one.
a. Transfer to another investigator, organization or person. Briefly describe subsequent treatment of the animal:

b. If animals must be permitted to die of experimentally induced conditions, including genetic abnormalities, justify the need for this requirement:

c. If the research involves the use of animals which have serious natural or experimental disease or deficit, the state of which would be maintained for an extended period, please justify:

Part IV: CONSIDERATIONS RELATED TO PAIN OR DISTRESS

27. Check the category which best describes the proposed research, and the number of animals in each category. For complex projects it may be desirable to provide the data for each experiment, if their classification varies. If animals are receiving multiple treatments, list them only once in the highest category which applies. For example, if 24 rats will be observed foraging for food, and 12 of those rats will be castrated, then 12 would be listed as (a) and 12 as (b).

a. Involves little or no pain, distress or discomfort (e.g., injections, blood sampling, blood pressure measurement, anesthetizing without recovery for organ removal, etc.

b. Involves short-term pain, pain, discomfort or distress which will be treated with appropriate anesthetics/analgesics (minor survival surgery with anesthesia and without significant postoperative pain, e.g. biopsy, implantation of peripheral chronic catheters, male gonadectomy in mammals.

c. Involves chronic maintenance of animals with a disease/functional deficit and/or procedures potentially inducing moderate pain, discomfort or distress which will be treated with appropriate anesthetics/analgesics (e.g. surgical procedures involving a body cavity; use of immunological adjuvants).

d. Potentially involves pain, discomfort or distress which cannot/will not be alleviated through the administration of appropriate anesthetic/analgesic or tranquilizing drugs.

28. For any treatments which may cause more than momentary or slight pain or distress, describe in sufficient detail for the Committee to understand what the animal will experience. Indicate how long the condition will be maintained, what agents will be used and who will be responsible. Justify the treatment in the context of the project. This requirement applies to all experiments involving pain, distress, and/or discomfort regardless of whether drugs are other methods are being used to attempt to alleviate the pain or distress.

29 Please indicate any of the following conditions applicable to your project.

a. Imposition of abnormal environmental conditions:

b. Nutritional stress. If food or water deprivation is involved, describe 1) the deprivation regimen used to bring the animal down to its goal weight, 2) the maintenance regime used to sustain that weight and 3) the procedures designed to monitor the general health and condition of the animal. Attach a copy of the record-keeping chart which will be posted in your animal room.

c. Use of:

☐ radioisotopes [Proposals that need radiation safety approval must be sent to Dr. Lynn Francesconi, Chairperson of the Radiation Safety Committee and to Environmental Health and Safety (EHS)]

☐ infectious agents, recombinant DNA [Proposals that need bio-safety approval must be sent to Dr. Robert Raffaniello, the Chairperson of the Institutional Biosafety Committee, and to Environmental Health and Safety (EHS)]

☐ carcinogens, toxins, or other hazardous materials [Proposals that need environmental and occupational safety approval must be sent to the Director of EHS.]

If yes to any check box please attach a copy of the approval from the appropriate committee or College official.

d. Single or multiple survival surgery. All survival surgery must be performed using aseptic procedures. This includes, in part, surgical gloves, masks, sterile instruments, and aseptic technique. Responses to sections 3 and 5 below must conform to institutional guidelines (http://research.hunter.cuny.edu/iacuc_guidlines.htm) unless compelling justification for deviation is provided.

1) Who will perform surgery?
2) In what room?
3) Pre-operative treatment (fasting, premedication including pre-emptive analgesics, anesthesia, preparation of surgical site)
4) Describe the surgical procedure (including individual responsible, site of incision, operative manipulations, method of closure, length of procedure, etc.)
5) Describe postoperative care (Individual responsible, monitoring recovery from anesthesia, use of analgesics, antibiotics, etc., fluids, suture removal, and monitoring for postoperative complications)
6) Potential postsurgical complications and how they will be addressed?
7) Should Facility staff notify the PI prior to emergency treatment?
8) Justify need to perform multiple survival surgery.

e. Non-survival surgery.

f. Other.

30. Pain and distress. (a) How will pain and distress be monitored (i.e., what criteria will be used to judge the presence and degree of pain and distress)? (b) What procedures are proposed for its alleviation?

To the researcher: Have you answered every question? Are your responses printed in a typeface which differentiates them from the questions? Do the numbers of animals per **group listed in 16, 18, and 23 agree?**

CERTIFICATION

I certify that the above information concerning procedures to be taken for the humane use of animals is, to the best of my knowledge, correct. I will seek and obtain prior approval for substantive modification of this protocol and will report promptly to the Institutional Animal Care and Use Committee any significant unanticipated distress caused to the animals.

I am familiar with the NIH Guide for the Care and Use of Laboratory Animals and the Public Health Service Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions. I will conduct my activities, whether of a research or instructional nature, in conformance with these regulations, policies, and principles.

Approval of this protocol is given subject to space in the animal facilities and personnel availability. It is my responsibility to contact the Manager of Animal Facilities concerning the timing of my project and the use of responsible vendors.

Finally, I understand that the protocol is subject to ongoing review, and a complete review is required within one year from the date of the previous approval.

Faculty Member Responsible Signature Date

Chair or Dean (Print) Signature Date

If this protocol covers an application for funding, I certify that the experimental design (i.e., number of experiments, precise experimental treatments, etc.) and methodology (e.g., how the treatments will be administered, drug doses, number of animals per group, numbers of pilot animals, etc.) of the protocol and the grant application agree in every detail.

Faculty Member Responsible Signature Date

Please send the completed form to the Office of Research Administration, Room 1425E.